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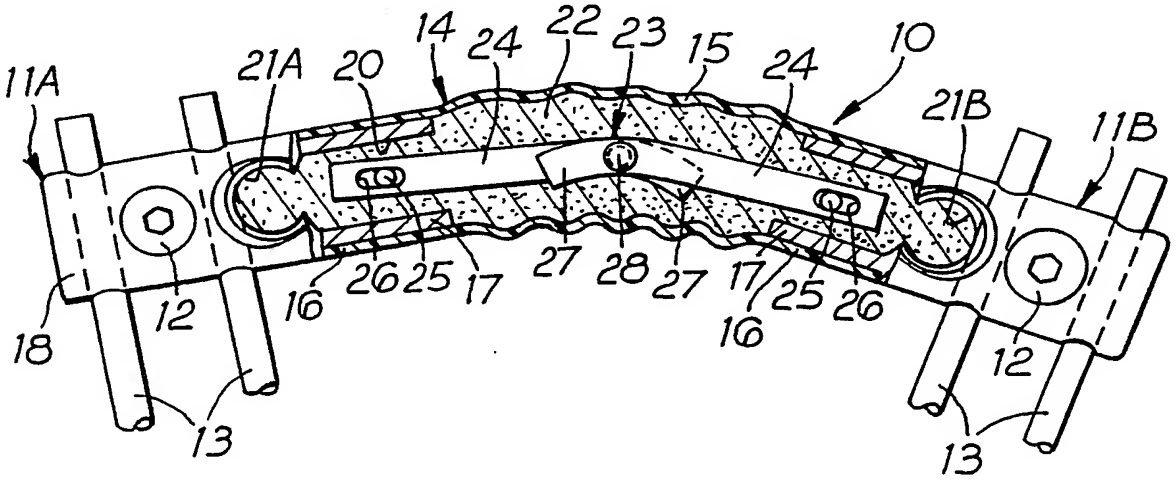
(54) Title: BONE FIXATION



(57) Abstract

A disposable bone fixator (10) has a pair of clamps (11A, 11B) each having means (12) for clamping two bone pins (13), together with sleeve (14) adapted to connect the clamps (11A, 11B) with each other in adjustable relative diposition, and two openings (21A, 21B) for the introduction into the sleeve (14) of a hardenable filler material (22) and expelling of air, whereby the filler material (22), when set, secures the clamps (11A, 11B) in their relative adjusted disposition when they have been clamped onto pairs of bone pins (13) screwed into bone portions at each side of a fracture.

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BONE FIXATION

This invention relates to bone fixation more particularly - but not exclusively - for the fixation of broken joints, e.g., wrists.

An object of the present invention is the avoidance of use of plaster casts, which cause irritation and other discomfort - even to the extent that the wearer interferes with the cast in an attempt to scratch the irritated skin or cut away a portion causing pressure.

Another object of the invention is to provide disposable bone fixators, low in cost yet very efficient and readily adaptable to various broken joints or bones.

According to the present invention, a bone fixator comprises a pair of clamps each having means for clamping at least two bone pins, together with sleeve means adapted to connect the clamps with each other in adjustable relative disposition, and at least one opening for the introduction into the sleeve means of a hardenable filler material for securing the clamps in their relative adjusted disposition when they have been clamped on to pairs of bone pins screwed into bone portions at each side of a fracture.

Obviously, the hardenable filler material should have a relatively short hardening time, e.g., five minutes, so that setting of the clamps with the bone portions and setting of the filler material in the sleeve means can be performed in the operating room, thus avoiding the need to transfer the patient to a plaster cast room, where application and setting of a plaster cast can be a lengthy and costly process.

Thereafter, the hardened filler material holds the clamps with the bone portions in the set position until the fracture has mended, when the clamps are released from the bone pins for disposal with the sleeve means, and the bone pins are unscrewed from the bone portions.

Two openings are preferably provided, one for introducing filler material into the sleeve means and the other to enable air to be expelled from the sleeve means, and also so that emergence at the other opening of filler material indicates that the sleeve means is full. Closure means is preferably provided for each opening or, if close enough, both openings together, particularly to prevent ingress of extraneous matter before use.

The sleeve means may be a flexible sleeve with its ends secured on spigots on the clamps, the flexible sleeve (which may be made of rubber or suitable plastics) allowing the clamps to be set with the bone portions in the appropriate relative dispositions (which will usually be at an angle to each other for fixation of a broken joint, but probably in line for fixation of a broken bone).

Each clamp conveniently comprises a pair of semi-cylindrical members, e.g., of die-cast aluminium alloy or of "rigid" plastics, e.g., an acetyl or nylon, one of which has the spigot integral with one end, and the mutually-facing flat surfaces may have aligned transverse grooves to each side of holes for a locking screw for effecting clamping of bone pins in the aligned grooves.

The spigots of the clamps may have coaxial blind bores

for location of reinforcement for the hardenable filler material, and such reinforcement may comprise a steel helical coil (e.g., a light compression spring). Alternatively, the reinforcement may comprise a pair of bars extending one from within each blind bore and overlapping each other, each bar being hingedly secured in the respective blind bore by means of a cross-pin and slot, and the overlapping portions of the bars being hinged together and bent beyond the hinge in the direction in which the sleeve is to be bent or curved. The blind bores and reinforcement therein assist with bonding of the hardenable filler material with the spigots and at least one but preferably each spigoted clamp member includes an opening to the blind end of the bore in the spigot for introducing the filler material and enabling air to be expelled.

The sleeve preferably includes at least one bellows-like portion to assist in bending or curving of the sleeve without kinking, and/or to allow of some stretching or contracting of the sleeve to suit the spacing of the clamps when fixed to bone pins already screwed into bone portions.

The outsides of the spigots may be ribbed (or grooved) circumferentially to assist securing of the ends of the flexible sleeve thereon, but adhesive may be used alternatively or additionally.

However, the sleeve means is preferably rigid and consists of at least two telescoping parts, one secured to or integral with a part of each clamp, the telescoping parts allowing some extending (or contracting) of the sleeve means

to suit the spacing of the clamps when fixed to bone pins already screwed into bone portions, the inner part having transversely extending projections - preferably provided by a pair of transverse holes - whereby the adjusted length of the sleeve means will be "frozen" by filler material when set in the sleeve means, and at least one telescoping part - conveniently the outer part - has its clamp connected by a ball joint, whereby the clamps can be set at an angle to each other (or in line) and "frozen" in that disposition by filler material when set in the sleeve means and around the ball, which preferably has means engageable by the filler material to lock the ball positively, and such locking means may comprise a blind bore in the ball or - preferably - transverse projections (e.g., ribs) on a pin extending from the ball.

The telescoping sleeve parts, ball joint, and clamp parts may be made as die-cast aluminium alloy parts or preferably of "rigid" plastics.

Each clamp conveniently comprises a pair of semi-cylindrical members, one of which is integral with one end of the sleeve or the ball of the ball joint, and the mutually-facing flat surfaces may have aligned transverse grooves to each side of holes for a locking screw for effecting clamping of bone pins in the aligned grooves, or bone pins may be clamped directly between the mutually-facing flat surfaces by a pair of locking screws.

A ball joint may be provided at the outer end of both telescoping sleeve parts, to allow of a greater angle between the clamps than one ball joint will allow.

Again, the rigid sleeve means may consist of three telescoping parts, preferably a central part with transversely extending projections in each tubular end, and a pair of outer tubular parts fitting one on each end of the central part, to allow of a greater extension of length than two telescoping parts will allow, and the central part may be provided centrally with a clamp having means for clamping at least two bone pins, to enable additional fixation to a particularly long broken bone or even a bone broken in two places.

A number of embodiments of the invention will now be described, by way of example only, with reference to the accompanying drawings, in which:-

Figure 1 is a part sectional side elevation of a bone fixator in accordance with the invention;

Figure 2 is a view partly in section on the line II-II of Figure 1, showing the fixator in operative condition;

Figure 3 is a small scale diagram showing the fixator of Figures 1 and 2 in relation to the bones of a hand with a Colles fracture;

Figure 4 is a longitudinal section through another fixator in accordance with the invention;

Figure 5 is a view, partly in section on the line V-V of Figure 4, showing that fixator in operative condition;

Figure 6 is a part sectional side elvation of a preferred form of bone fixator in accordance with the invention;

Figure 7 is a view, partly in section on the line VII-VII of Figure 6, showing the preferred embodiment of fixator

in operative condition; and

Figures 8 and 9 are respective part sectional side elevations of two further embodiments of the invention, with Figure 9 on a smaller scale than Figures 1 and 2 or Figures 4 to 8.

In Figures 1 and 2 a bone fixator 10 comprises a pair of clamps 11A, 11B each having a screw 12 for clamping two bone pins 13, together with sleeve means 14 consisting of a flexible sleeve of rubber (or alternatively, suitable plastics) connecting the clamps and having a bellows portion 15 whereby the clamps are adapted to be disposed at an angle to each other, e.g., as shown in Figure 2, and allowing some stretching or contracting of the sleeve to suit the spacing of the clamps when fixed to bone pins already screwed into bone portions e.g., as shown in Figure 3.

End portions 16 of the sleeve 14 are secured (e.g., by adhesive) on spigots 17 integral with one semi-cylindrical member 18 in each clamp 11A, 11B, the clamp members 18, 19 being formed of die-cast aluminium alloy (or, alternatively, of rigid plastics) with aligned grooves in their mutually-facing flat surfaces to each side of holes for the locking screw 12 for effecting clamping of the bone pins 13 in the aligned grooves.

The spigots 17 have coaxial blind bores 20 communicating with openings 21A, 21B, one for introducing hardenable filler material 22 (Figure 2) into the sleeve 14 and the other to enable air to be expelled from the sleeve and also so that emergence at that other opening of filler

material indicates that the sleeve is full. The hardenable filler material, when set, secures the clamps in their relative adjusted positions, as indicated in Figures 2 and 3.

Reinforcement 23 for the filler material consists of a pair of bars 24 extending one from within each blind bore 20 and overlapping each other, each bar being hingedly secured in the respective blind bore by means of a cross-pin 25 and slot 26, and the overlapping portions 27 of the bars being hinged together and bent beyond the hinge 28 in the direction in which the sleeve 14 is to be bent or curved.

Closure plugs 29 (Figure 1) are provided for the openings 21A, 21B to prevent ingress of extraneous matter before use.

In Figures 4 and 5 a bone fixator 30 comprises a pair of clamps 11A, 11B with screws 12 for clamping bone pins 13, together with sleeve means 14 consisting of rigid telescoping parts 31, 32, one integral with one part 18 of the clamp 11A and the other connected by a ball joint 33 to the clamp 11B, whereby the clamps are adapted to be disposed further apart and/or at an angle to each other, e.g., as indicated in Figure 5.

An opening 21A communicates with the inside of the sleeve part 31, while an opening 21B communicates via a bore 34 through the ball 35 of the ball joint 33 with the inside of the sleeve part 32, whereby hardenable filler material 22 (Figure 5) can be introduced through one opening and air expelled through the other, emergence of filler material at that other opening indicating that the sleeve parts are full.

The filler material, when set, secures the sleeve parts 31, 32 in their extended relative disposition, and secures the ball joint 33 and the clamp 21B in their angled disposition relative to the sleeve parts and the clamp 21A.

Closure plugs 29 are again provided for the openings 21A, 21B to prevent ingress of extraneous matter before use.

In the preferred embodiment of bone fixator 40 shown in Figures 6 and 7, sleeve means 14 again consists of telescoping parts 31, 32, one integral with one part 18 of the clamp 11A and the other connected by a ball joint 33 to the clamp 11B, but the inner sleeve part 31 has transversely extending projections provided by a pair of transverse holes 41, whereby the adjusted length of the sleeve means 14 will be "frozen" by filler material 22 (when set) introduced through an opening 42 in the outer sleeve part 32 adjacent the ball joint 33 and alongside which is a smaller opening 43 through which air is expelled and at which filler material will eventually emerge to indicate that the sleeve means 14 is full. Also, the ball 35 is locked positively by filler material 22 setting around a pin 44 with ribs 45 extending from the ball. Both openings 42, 43 can be closed by a rotatable cover 46 to prevent ingress of extraneous matter before use.

In Figure 8 the fixator 50 has its inner telescoping part 31 also connected to the clamp 11A by a ball joint 33X, the ball 35X of which likewise has a projecting pin 44X with ribs 45X, and another small opening 51 is provided adjacent the additional ball joint so that emergence of filler material

at the opening 51 will indicate that filler has reached and surrounded the pin 44X and ribs 45X. A groove 52 along the outside of the inner telescoping part 31 is slidably engaged by a peg 53 projecting from the outer telescoping part 32, to ensure that the opening 51 remains uppermost along with the openings 42, 43 adjacent the ball joint 33.

Figure 8 also shows smaller bone pins 13 clamped directly between the mutually-facing flat surfaces of the clamp parts 18, 19 by a pair of locking screws 12 (see particularly the clamp 11B which has been shown turned through 90° about the longitudinal axis).

In Figure 9 the fixator 60 comprises sleeve means 14 consisting of two outer telescoping parts 32A, 32B (similar to the part 32 in Figures 6, 7 and 8) and a central part 61 with transversely extending holes 41 in each tubular end 62 slidable within the parts 32A, 32B respectively, to allow of a greater extension of length than two telescoping parts will allow, and the central part may be provided centrally with a clamp (not shown) for at least two bone pins, to enable additional fixation to a particularly long broken bone or even a bone broken in two places.

Although the rigid telescoping sleeve means 14 could be made of die-cast aluminium alloy, they are preferably made of "rigid" plastics (as indicated in Figures 6 to 9), which enables a small G-clamp to be applied to the outside of the or each ball joint 33, 33X to lock the ball 35, 35X and its associated clamp 11B, 11A in the required position while the hardenable filler material 22 sets to secure the fixator in

the required dipsosition. Likewise, the clamp parts 18, 19 and associated ball 35, 35X can be made of "rigid" plastics, only the bone pins 13, locking screws 12, and locking pins 44, 44X then being of metal.

CLAIMS

1. A bone fixator comprising a pair of clamps each having means for clamping at least two bone pins, together with sleeve means adapted to connect the clamps with each other in adjustable relative disposition, and at least one opening for the introduction into the sleeve means of a hardenable filler material for securing the clamps in their relative adjusted disposition when they have been clamped on to pairs of bone pins screwed into bone portions at each side of a fracture.

2. A bone fixator as in Claim 1, wherein two openings are provided.

3. A bone fixator as in Claim 2, wherein closure means is provided for each opening or both openings together.

4. A bone fixator as in any one of Claims 1 to 3, wherein the sleeve means is a flexible sleeve with its ends secured on spigots on the clamps.

5. A bone fixator as in Claim 4, wherein each clamp comprises a pair of semi-cylindrical members one of which has the spigot integral with one end.

6. A bone fixator as in Claim 5, wherein the mutually-facing flat surfaces have aligned transverse grooves to each side of holes for a locking screw for effecting clamping of bone pins in the aligned grooves.

7. A bone fixator as in any one of Claims 4 to 6, wherein the spigots of the clamps have coaxial blind bores for location of reinforcement for the hardenable filler material.

8. A bone fixator as in Claim 7, wherein the

reinforcement comprises a steel helical coil.

9. A bone fixator as in Claim 7, wherein the reinforcement comprises a pair of bars extending one from within each blind bore and overlapping each other, each bar being hingedly secured in the respective blind bore by means of a cross-pin and slot, and the overlapping portions of the bars being hinged together and bent beyond the hinge in the direction in which the sleeve is to be bent or curved.

10. A bone fixator as in any one of Claims 4 to 9, wherein the sleeve includes at least one bellows-like portion to assist in bending or curving of the sleeve without kinking, and/or to allow of some stretching or contracting of the sleeve to suit the spacing of the clamps when fixed to bone pins already screwed into bone portions.

11. A bone fixator as in any one of Claims 1 to 3, wherein the sleeve means is rigid and consists of at least two telescoping parts, one secured to or integral with a part of each clamp, the telescoping parts allowing some extending of the sleeve means to suit the spacing of the clamps when fixed to bone pins already screwed into bone portions, the inner part having transversely extending projections whereby the adjusted length of the sleeve means will be "frozen" by filler material when set in the sleeve means and at least one telescoping part has its clamp connected by a ball joint, whereby the clamps can be set at an angle to each other and "frozen" in that disposition by filler material when set in the sleeve means and around the ball.

12. A bone fixator as in Claim 11, wherein the

inner telescoping part has a pair of transverse holes.

13. A bone fixator as in Claim 11 or Claim 12, wherein the ball has means engageable by the filler material to lock the ball positively.

14. A bone fixator as in Claim 13, wherein the said locking means comprises a blind bore in the ball.

15. A bone fixator as in Claim 13, wherein the said locking means comprises transverse projections on a pin extending from the ball.

16. A bone fixator as in any one of Claims 11 to 15, wherein the telescoping sleeve parts, ball joint, and clamp parts are made of "rigid" plastics.

17. A bone fixator as in any one of Claims 11 to 16, wherein each clamp comprises a pair of semi-cylindrical members, one of which is integral with one end of the sleeve or the ball of the ball joint.

18. A bone fixator as in Claim 17, wherein the mutually-facing flat surfaces have aligned transverse grooves to each side of holes for a locking screw for effecting clamping of bone pins in the aligned grooves.

19. A bone fixator as in any one of Claims 11 to 18, wherein a ball joint is provided at the outer end of both telescoping sleeve parts.

20. A bone fixator as in any one of Claims 11 to 19, wherein the rigid sleeve means consists of three parts a central part with transversely extending projections in each tubular end, and a pair of outer tubular parts fitting one on each end of the central part.

21. A bone fixator as in Claim 20, wherein the central part is provided centrally with a clamp having means for clamping at least two bone pins.

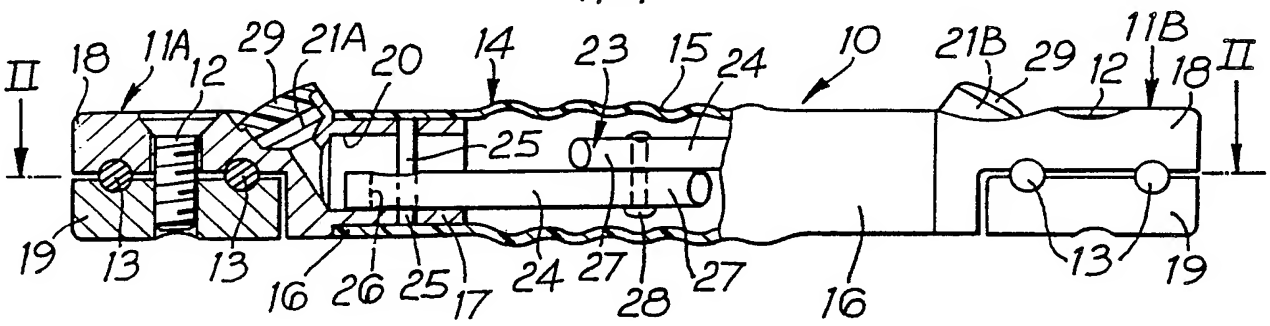


Fig. 1

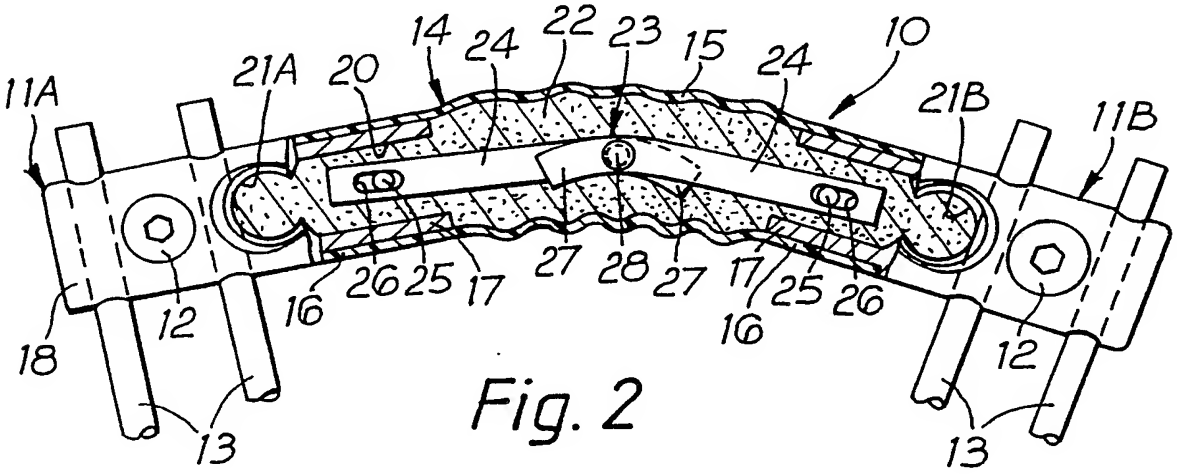


Fig. 2

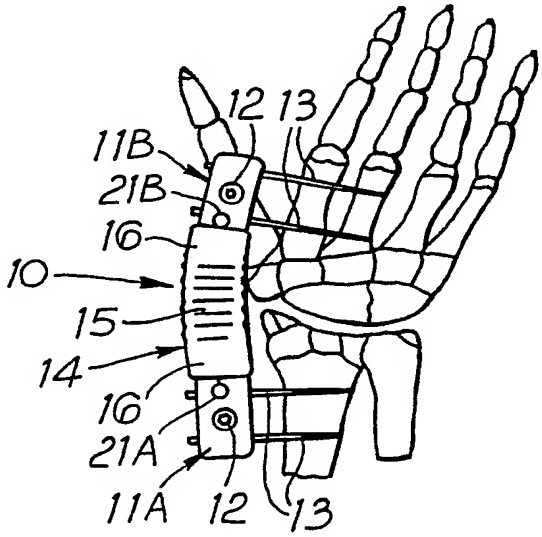
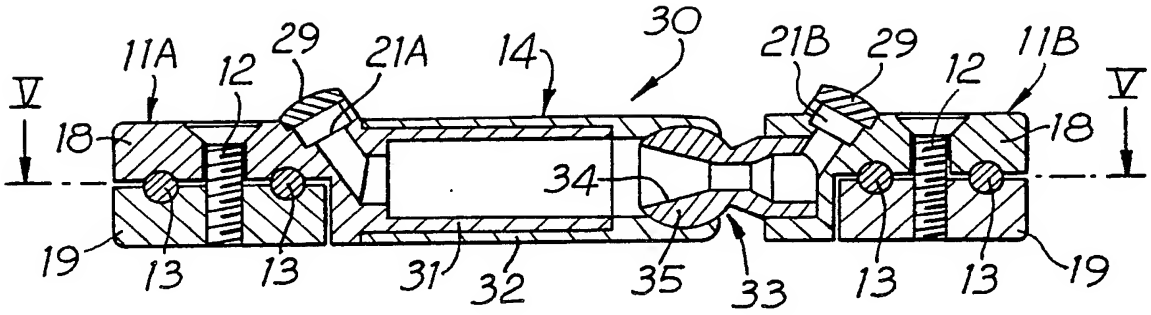


Fig. 3


11A
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21A
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Fig. 4

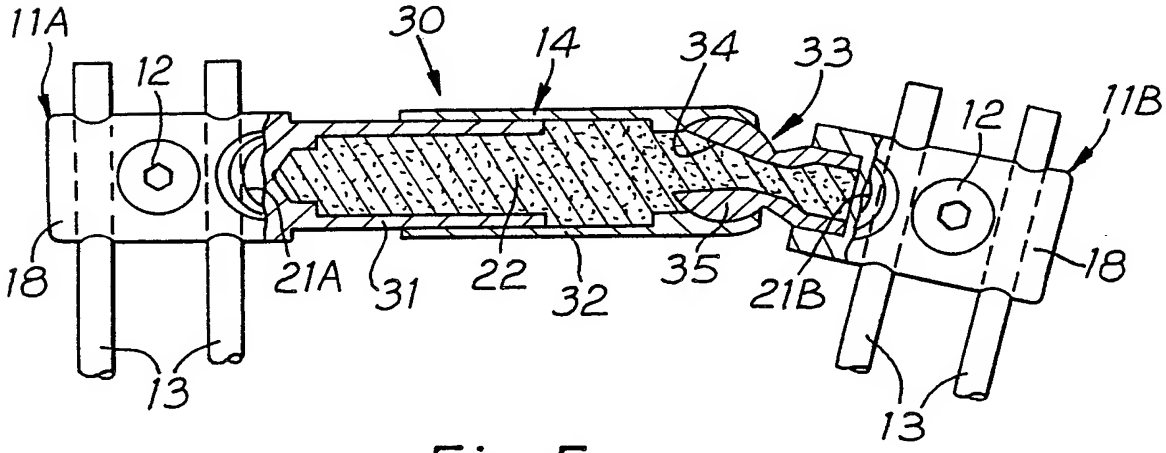
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Fig. 5

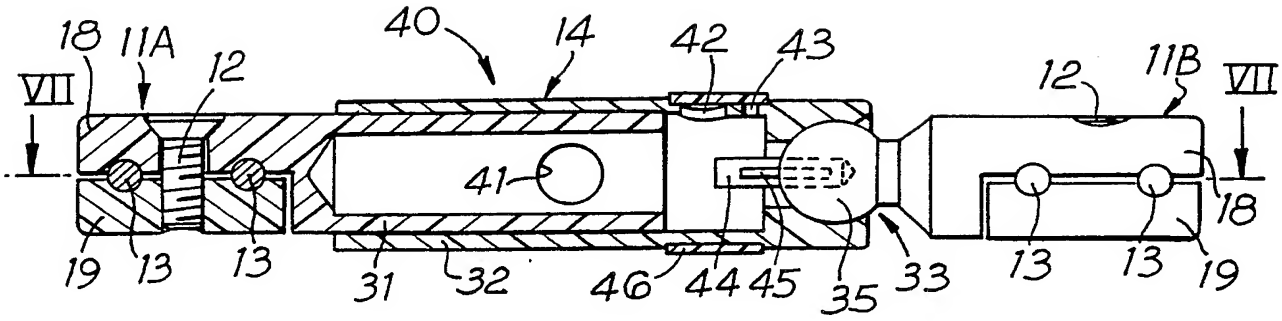
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Fig. 6

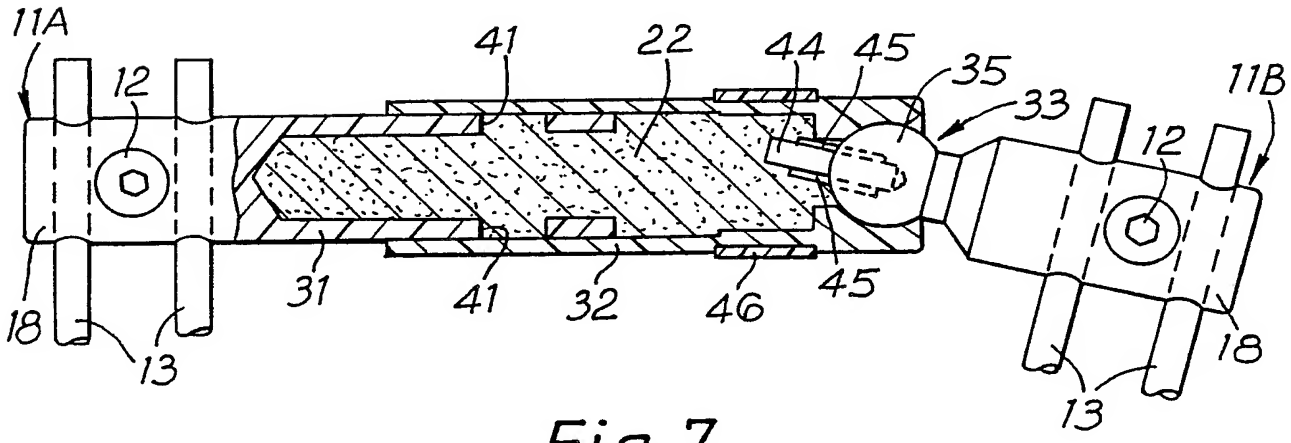
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Fig. 7

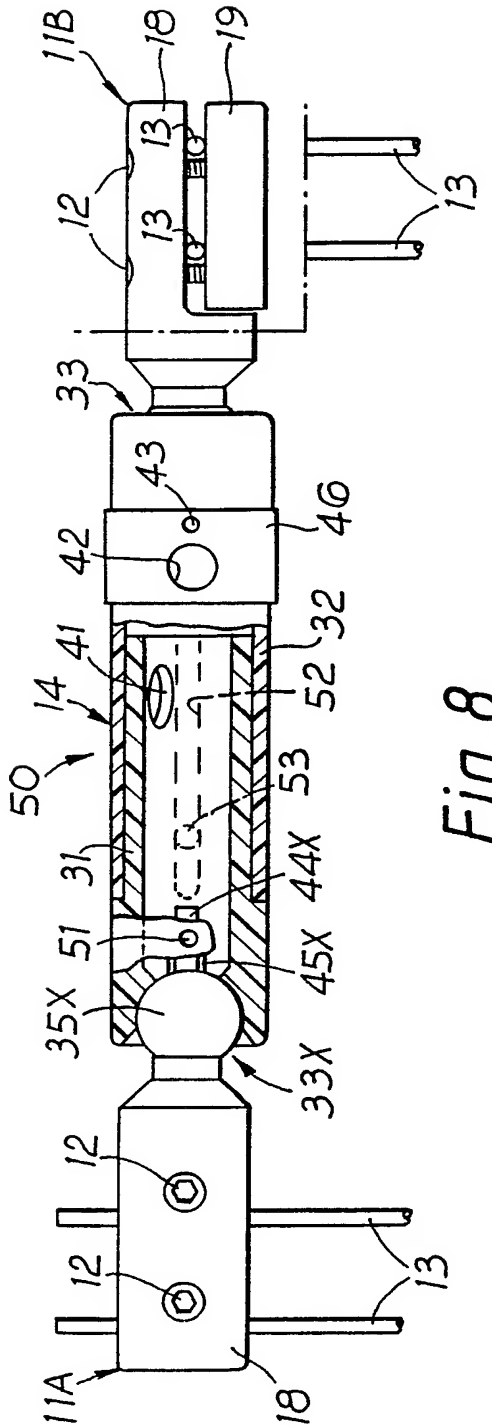
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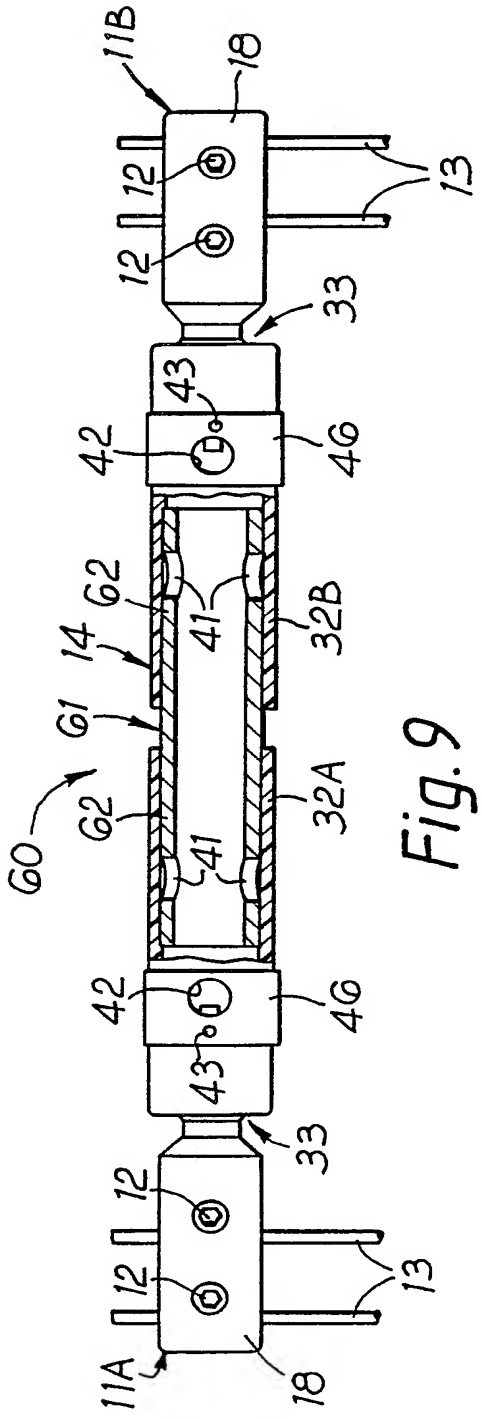
Fig. 8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46
43
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12
12
13
11A
18

Fig. 9

INTERNATIONAL SEARCH REPORT

International Application No PCT/GB 89/00309

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC[4]: A 61 B 17/60

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
IPC[4]	A 61 B

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category [10]	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
Y	EP, A, 0011258 (ORTHOFIX) 28 May 1980, see page 5, lines 1-32; page 8, line 26 - page 9, line 5; figures 1-4	1-3,11, 17-20
A	--	5,6,9
Y	EP, A, 0260484 (HERZBERG) 23 March 1988, see column 9, line 44 - column 10, line 3; column 11, line 28 - column 12, line 21; column 13, line 43 - column 16, line 40; column 19, line 21 - column 22, line 10; figures 1-5,9-11,14-16	1-3,11, 17-20
A	--	4,7
A	GB, A, 1492681 (MURRAY) 23 November 1977, see page 1, lines 34-69; page 2, lines 30-85; figures 1,2,9	1,4,9
A	--	
A	GB, A, 2086231 (N.R.D.C.) 12 May 1982, see page 1, lines 78-91; abstract; figure 1	1,4,10
	.-- ./.	

* Special categories of cited documents: [10]

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"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
20th July 1989	11 AOUT 1989
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	M. VAN MOL

Form PCT/ISA/210 (second sheet) (January 1985)

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

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ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. GB 8900309 SA 27738

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 08/08/89
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